IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STROM ex rel. UNITED STATES OF AMERICA,

Plaintiff,

v.

SCIOS, INC. ET AL.,

Defendants.
_____/

No. C 05-3004 CRB

ORDER DENYING MOTION TO DISMISS

This case involves allegations by the United States that Defendants Scios Inc. and Johnson & Johnson (collectively, "Defendants") fraudulently caused thousands of doctors to submit false claims for reimbursement under Medicare and other federally organized health programs.[1] The United States argues that this scheme violated the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1). Defendants move to dismiss under Rule 12(b)(6) for failure to state a claim and under Rule 9(b) for failure to make allegations with sufficient particularity. As to the 12(b)(6) arguments, Defendants contend that the claims submitted by doctors to Medicare were not actually false, and that the False Claims Act should not be used to second guess decisions made by doctors. As to the 9(b) arguments, Defendants contend

[1] While the vast majority of claims at issue in this case were submitted to Medicare, the Complaint also alleges fraud with regard to claims submitted to the TRICARE program, 10 U.S.C. § 1071 *et seq.*, and the Federal Employee Health Benefits Program, 5 U.S.C. § 8901 *et seq.* The parties do not dispute that the relevant standards for off-label coverage are materially similar, and Defendants' motion addresses all claims together. Therefore, this order discusses all claims generally as "Medicare" claims.

that the Complaint fails sufficiently to specify the details of the individual claims and that the claims were extrapolated from an insufficiently precise algorithm. Further, Defendants argue that the Complaint fails to allege a causal link between Defendants' actions and the submission of some of the claims to Medicare and other federal programs.

Plaintiff's complaint seeks relief based on a relatively novel theory. While a few district courts across the country have considered analogous complaints, there is little circuit-level authority. For the reasons explained below, Defendants' motion to dismiss is DENIED. While Defendants' arguments may gain more traction at the summary judgment stage or at trial, at present the Complaint sufficiently alleges a cause of action under the FCA.

BACKGROUND

Because this case comes before the Court on a motion to dismiss, we begin by summarizing the extensive allegations contained in the Complaint. As described below, the material allegations revolve around whether or not Defendants induced doctors to prescribe their drug – Natrecor – for a use that was not medically accepted. Natrecor was certified by the FDA as effective when used for episodes of "acutely decompensated congestive heart failure," but Plaintiff alleges that Defendants recklessly encouraged doctors to prescribe the drug for non-acute episodes. Plaintiff argues that use of this drug for non-acute episodes was not medically accepted, and therefore was not eligible for reimbursement under Medicare or other federal health care programs.

Scios developed a drug called Natrecor in the 1990s "for the short-term treatment of patients with acutely decompensated congestive heart failure ('ADHF'). Decompensation means that the patient's lungs have accumulated fluid." Comp. ¶ 39. In August 2001, based on the results from a recent clinical study, the FDA approved Natrecor for a limited use. The FDA-approved label read as follows:

> Natrecor (nesiritide) is indicated for the intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity. In this population, the use of Natrecor reduced pulmonary capillary wedge pressure and improved dyspnea.

Id. ¶ 43 (emphasis added). In the context of Medicare reimbursement, use of Natrecor for the purpose listed on the label constitutes "on-label" coverage. Medicare coverage for the use of

Natrecor for any other purpose constitutes "off-label" coverage. While Medicare does indeed cover off-label uses of drugs in some contexts, the Medicare Benefits Policy Manual provides that the coverage "of an outpatient drug for an off-label use occurs only where the use is medically accepted, taking into account the major drug compendia, (*e.g.*, Drugdex, American Hospital Formulary Service, and U.S. Pharmacopeia-Drug Information), authoritative medical literature, and/or accepted standards of medical practice." Id. ¶ 30. As Defendants explain, this "medically accepted" terminology clarifies the applicable statutory language, which provides coverage for uses that are "reasonable and necessary." See 42 U.S.C. § 1395y(a)(1)(A); see also Nat'l Med. Enters. v. Bowen, 851 F.2d 291 (9th Cir. 1988) ("The [Medicare] Manual is a guide for intermediaries in applying the Medicare statute and reimbursement regulations and does not have the binding effect of law or regulation.").

A short time after Natrecor's approval, Scios started what was known as "the FUSION I trial." Id. ¶ 48. The name "FUSION I" was derived from the study's full name: "Management of Heart Failure after Hospitalization with Follow Up Serial Infusions of Nesiritide in an Outpatient Setting." Id. (emphasis added). As explained more thoroughly below, Plaintiff alleges that this outpatient use of Nesiritide constitutes an "off-label" use of the drug because it was not limited to "acute" episodes of congestive heart failure. Further, Plaintiff alleges that such a use was not reasonable and necessary. "FUSION I was a pilot study designed only to assess the ability of a patient with chronic congestive heart failure to tolerate . . . the safety of serial infusions . . . and thus was not a study that could be used to determine the efficacy of the serial infusions." Id. According to the Complaint, despite the fact that the FUSION I study was not designed to assess the efficacy of outpatient use of Nesiritide, Scios announced in a widely disseminated press release that "[d]ata from the FUSION I study suggests that the Natrecor-treated patients show improvements in clinical status with longer life expectancy and a lower frequency of hospitalizations compared to the group of patients receiving standard care." Id. ¶ 51. Plaintiff alleges that, because of the limited nature of the FUSION I study, such a claim was scientifically unsupported.

The Complaint alleges that this press release, in conjunction with the various other marketing activities described below, shows that Defendants were encouraging a use of the drug that was not authorized by the FDA. This is so, explains the Government, because an outpatient use of the drug is inherently inconsistent with the "acutely decompensated congestive heart failure" that is listed on the FDA label.

> By definition, an acute episode of decompensated [congestive heart failure] with dyspnea at rest or with minimal activity is an emergency situation that does not occur on a scheduled basis. . . . Defendants knew that outpatient infusions would generally not be for the acutely decompensated patients described in Natrecor's label, except in the rare circumstance when an acutely decompensated patient with dyspnea at rest or with minimal activity sought care from a doctor's office or clinic instead of a hospital or emergency room.

Id. ¶ 57-58. Because these outpatient infusions would generally not occur in emergency situations, Plaintiff contends that use of the drug in such a context almost always constitutes an off-label use. Id. ¶ 58.

Plaintiff further alleges that Defendants were aware that outpatient use constituted an off-label use. "At Scios's October 2003 National Sales Meeting, Cox noted that half of the Natrecor business was coming from the outpatient segment, and that Natrecor would ultimately go from an acute medication to a chronic medication. He further noted that the outpatient serial dose of Natrecor used for FUSION I was not within the label." Id. ¶ 60. Similarly,

> at Scios's April 2002 National Sales Meeting, Scios Marketing Director George Mahaffey stated that intermittent infusions were not on label, and characterized the FUSION I study as off label. In a February 10, 2003 public conference call by Scios and J&J regarding their acquisition agreement, George Schreiner, Scios's Vice President and Chief Scientific Officer, said that the outpatient use of Natrecor which was being studied in the FUSION I trial 'of course is not currently within label but we are conducting the appropriate studies to potentially make it eligible for label extension.

Id. ¶ 61.

As noted above, Plaintiff also alleges that Defendants went to great efforts to market Natrecor for these off-label uses despite the absence of medical evidence supporting its efficacy for such uses. "A draft of the Natrecor 2003 Business Plan (reviewed by Scios CEO Richard Brewer) listed as one of Scios's 2003 objectives: 'Achieve 2% penetration of the patients treated serially via outpatient infusion for CHF by year-end 2003,' and as one of its

long-term objectives: 'Develop the outpatient infusion market and achieve at least 15% penetration of the estimated 145k patients treated with serial outpatient infusion by 2007." Id. ¶ 63. "On June 6, 2002, Kim Hillis, Scios's Director of Sales, wrote to the sales management with her thoughts on the areas where Scios's marketing, clinical, and sales efforts should be directed to achieve $1 billion in annual sales of Natrecor. Outpatient infusion was the first area Hillis listed." Id. ¶ 65. Defendants pursued these objectives despite the fact that "the off-label use was unsupported by *any* credible study showing that the serial outpatient infusions had any benefit for patients." Id. ¶ 5.

As for particular marketing efforts, Plaintiff alleges that Defendants relied on a variety of marketing strategies to promote use of Natrecor in the outpatient context. First, "Defendants encouraged health care providers to start outpatient infusion clinics that used Natrecor. For example, Defendants paid grant funds and provided other resources to health care providers to use in starting outpatient infusion clinics." Id. ¶ 71. Moreover,

> [i]n approximately late 2002 or early 2003, at a sales management meeting in Dallas, management was told to direct the sales representatives to '[a]ggressively pursue business' in the outpatient infusion market. During a sales representative training session in February 2004, Defendants discussed separate sales goals for 'Acute CHF' sales, and 'Outpatient' sales, and their plan to continue marketing Natrecor for outpatient use by 'establish[ing] a growing prescriber and advocate base that will drive Natrecor as the preferred management strategy in the outpatient setting.'

Id. ¶ 74.

In addition to simply focusing sales resources on expanding the outpatient market, Defendants also paid health care professionals to encourage further use of Natrecor in outpatient contexts. "From 2003 to 2005, Defendants paid over $100,000 to a nurse at South Bay. This nurse made promotional speeches relating to the outpatient use of Natrecor; she trained other health care providers on the outpatient use of Natrecor; and her name appears as author on various publications relating to the outpatient use of Natrecor, including, *inter alia*, 'Nesiritide in an Outpatient Infusion Clinic Setting - Case Studies of 17 patients' . . . ." Id. ¶ 76. Moreover, "Defendants paid numerous other health care professionals who authored articles, made promotional speeches, and taught continuing medical education courses that promoted the outpatient use of Natrecor." Id. ¶ 77. The Complaint lists a series of examples

at paragraphs 78 through 80. The complaint further alleges that Defendants encouraged this use of Natrecor "for serial infusions despite the lack of any scientific evidence to support the efficacy of such treatment." Id. ¶ 81.

Next, the Complaint alleges that "Defendants also encouraged scheduled outpatient infusions of Natrecor through their Centers of Excellence (later renamed Commitment to Excellence) Program." Id. ¶ 82.

> Under this program, Defendants sent health care practitioners who were potentially interested in starting outpatient infusion clinics to existing outpatient clinics that used Natrecor, in order to observe and learn. For example, prior to opening their own outpatient clinics, doctors and nurses from New York and Rhode Island visited South Bay to meet with the South Bay nurse and see how the South Bay clinic operated. At least three of the doctors who met with the nurse and then opened their own outpatient clinic each subsequently submitted claims to Medicare totaling more than $500,000 for serial, outpatient infusions of Natrecor. In a November 19, 2003 presentation to J&J officials, Scios officials acknowledged that Natrecor outpatient infusions were due in part to the Centers of Excellence program.

Id. ¶ 82. Defendants also "hired a company called Ingenix to ghostwrite articles about Natrecor, including its outpatient use, and arranged to submit them for publication in journals. Ingenix wrote the articles and Defendants selected the doctors and nurses to place their names on the articles as 'authors.'" Id. ¶ 84.

The Complaint further alleges that Defendants were well aware of the frequency with which heart failure patients – Natrecor's customers – were covered by Medicare. "A presentation at the August 2001 Natrecor launch National Sales Meeting by Scios Vice President of Sales and Marketing Tom Feldman noted that '[o]ver 80% of the [congestive heart failure] patient population is over 65 years old.' That same presentation noted that Medicare paid for 72.98% of the claims for [congestive heart failure] diagnosis code (ICD-9) 428.0, and stated that [congestive heart failure] is the '[s]ingle largest expense for Medicare.'" Id. ¶ 91. Because such a large number of Natrecor recipients were covered by Medicare, "Defendants established a reimbursement team, headed by Christopher Panarites, to handle reimbursement issues and the Medicare Contractors' local coverage determinations ('LCDs') regarding Natrecor. The main objective of Mr. Panarites's job was to maintain unrestricted access to Natrecor in the outpatient setting." Id. ¶ 94.

The Complaint notes that Scios, "without any scientific support for the efficacy of the serial infusions, urged Medicare Contractors to cover serial outpatient infusions." Id. ¶ 106. In particular, the Complaint explains that "Scios routinely touted both the safety and alleged efficacy results of the limited FUSION I study to the Medicare Contractors in an effort to support coverage." Id. As a result, "Five Medicare Contractors (three in the New York region) issued Local Coverage Determinations ('LCDs') allowing limited coverage for the outpatient serial use of Natrecor . . . ." Id. "A number of other Medicare Contractors specifically denied coverage for this use." Id. On May 17, 2005, a number of these Contractors "submitted a formal request to [the Centers for Medicare & Medicaid Services] for a National Coverage Determination ('NCD') on Natrecor, noting that 'the specific reason for our NCD request focuses on the 'off-label' use of intravenous Nesiritide' . . . ." Id. ¶ 106. In March of 2006, the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare Program, determined that Medicare coverage would be unavailable for this off-label use. The CMS explained that

> Much of the reported research on the use of nesiritide for the intermittent treatment of chronic heart failure appears in abstracts and has not yet been published as full peer-reviewed journal articles. In general, abstracts do not provide sufficient information for us to evaluate the strength of the reported findings critically. . . . The published articles . . . supporting the off-label use of nesiritide for chronic heart failure are hampered by methodological shortcomings, including small sample size and the lack of long term outcome data.

Id. ¶ 114.

The Complaint asserts two causes of action: presentation of false claims to the United States government in violation of the False Claims Act, and Unjust Enrichment. As to the False Claims Act claim, the Complaint specifically alleges that "Scios and J&J knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for the scheduled, serial use of Natrecor that were not covered by the federal health care programs." Id. ¶ 122. As to the claim for Unjust Enrichment, the Complaint relies upon the presentation of false claims to argue that "Scios and J&J were unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity an good conscience, should be returned to the United States." Id. ¶ 125.

DISCUSSION

Defendants move to dismiss. First, they argue that the United States has failed to satisfy the pleading requirements of the False Claims act. This is so, they contend, because the Complaint does not allege that the claims submitted to Medicare violated any bright-line rule. The conduct alleged, argue Defendants, is better regulated by means other than the False Claims Act. For the reasons explained more thoroughly below, this motion is DENIED. The Complaint sufficiently alleges that Defendants' reckless misrepresentation of scientific evidence caused doctors to submit claims for treatment that were not reasonable and necessary, and hence were not eligible for reimbursement under Medicare.

Second, Defendants argue that Plaintiff fails to plead the FCA cause of action with sufficient particularity, and ask this Court to dismiss the Complaint under Rule 9(b). This argument, too, is DENIED.

1. Statutory Background and Applicability to Pharmaceuticals

Before addressing the specific arguments made by Defendants, it will be helpful to outline both the provisions of the False Claims Act, and a case that has addressed its application to the pharmaceutical context.

The Complaint proceeds under one section of the False Claims Act. That section, codified at 31 U.S.C. § 3729(a)(1)(A), provides that any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment . . . , is liable to the United States government for a civil penalty of not less than $5,000 and not more than $10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person." Id. A person "knowingly" presents a false claim when that person "has actual knowledge of the information[,] acts in deliberate ignorance of the truth or falsity of the information[,] or acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b)(1)(A)(i)-(iii).

A small number of district court orders from across the country have addressed the pleading requirements of this act in the pharmaceutical context. Among the most famous of these is United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001).

In Parke-Davis, the relator alleged that the defendant had engaged in a fraudulent scheme to promote the sale of Neurontin for off-label uses. The complaint alleged that this scheme caused the submission of false claims to Medicaid. The defendant argued *inter alia* that the complaint was an attempted "end-run around the enforcement provisions of the FDCA by creating a cause of action for money damages." Id. at 51. While the court agreed that the FCA could not be converted into a private right of action to remedy all violations of regulatory law, it concluded that "the FCA *can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation[] made to obtain a government benefit. Thus, the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government . . . ." Id. (citations omitted).

The defendant also argued that the complaint had not "accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions." Id. at 52. The court rejected this argument, noting that "[u]nder black letter law . . . such an intervening force only breaks the causal connection when it is unforeseeable." Id. (citing Dobbs, et al., *Prosser and Keeton on Torts* § 44, at 303-04 (5th ed. 1984)). In the context of that case, "when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." Id. at 52-53.

The district court declined to dismiss the case.

2. Defendants' Arguments Under Rule 12(b)(6)

Defendants' memorandum in support of dismissal under Rule 12(b)(6) urges this Court to conclude that "the False Claims Act only applies where there is a bright line rule." Mot. at 7. Defendant goes on to cite to a variety of cases for the proposition that "the False Claims Act has historically been applied in cases involving patently obvious falsehoods." Id. Indeed, Defendants surely are correct that the "archetypal *qui tam* FCA action . . . [is] filed

by an insider at a private company who discovers his employer has overcharged under a government contract." Id. (quoting United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996)).

However, Defendants overstate their claim. Defendants repeatedly urge this Court to require an allegation of "an objective lie" that a defendant "knows to be false," Mot. at 7, but Defendants fail to cite or acknowledge the statutory definition of "knowing." In contrast to Defendants' implications, the FCA defines "knowing" to include a defendant who "acts in deliberate ignorance of the truth or falsity of the information" and a defendant who "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729. This statutory definition broadens the reach of the FCA beyond what Defendants suggest is its outer limit. While Defendant is correct that FCA cases frequently rely on the word "lie," it is clear that this term is used to address the falsity of a claim, rather than whether the defendant has actual knowledge of falsity. Adopting the latter as the benchmark for FCA claims would directly conflict with the statutory language, and this Court therefore rejects the invitation to do so.

Given this broader definition of "knowing," Plaintiff has succeeded in stating a claim under the FCA. In sum, the Government alleges that Defendants' marketing activities created the market for the outpatient use of Natrecor, and that Defendants encouraged such a use even though they had no credible evidence that Natrecor was effective in that context. Because Defendants had no evidence supporting the efficacy of Natrecor in the outpatient context, Plaintiff effectively alleges that they acted in reckless disregard of the truth when they encouraged submission of such claims to Medicare. See 31 U.S.C. § 3729(a)(1)(A) (extending liability to parties who "caused to be presented" a false claim for payment). "Reckless disregard" satisfies the "knowing" element of an FCA action. See 31 U.S.C. § 3729(b)(1).

Further, Plaintiff alleges that the drug was not, in fact, effective when used for the off-label purpose. Because the statute permits reimbursement only for "reasonable and necessary" treatments, 42 U.S.C. § 1395y, a prescription of Natrecor in a context where it is

not "reasonable" or "necessary" would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a "false" statement.[2]

As to evidence of Defendants' reckless disregard, Plaintiff points first to the FUSION I study, which was allegedly the central piece of evidence used by Defendants to support outpatient use of Natrecor. The Complaint alleges that this study "was not a study that could be used to determine the efficacy of the serial [outpatient] infusions." Comp. ¶ 48. Plaintiff alleges that the truth of the matter is that Natrecor is simply not effective in the outpatient setting: a later study, properly designed to isolate the efficacy of the drug, "did not show any significant benefits of serial outpatient Natrecor infusions in comparison to standard care." Id. ¶ 54. Therefore, alleges Plaintiff, use of Natrecor in that setting could not be "reasonable and necessary" as required by Medicare.

Defendants suggest that they are shielded from liability because there was no clear evidence demonstrating that Natrecor was not suited to outpatient use, and further because a number of regional Medicare Contractors authorized reimbursement for outpatient use of Natrecor. This argument both overstates the FCA's "knowledge" requirement and understates the breadth of Plaintiff's allegations. First, as to whether there was "clear evidence" demonstrating that Natrecor was not suited to outpatient use, such evidence is unnecessary. While Defendants are correct that such evidence would establish that Defendants "had actual knowledge" that Medicare would not pay for outpatient uses of Natrecor, the FCA simply does not require "actual knowledge." As discussed above, the FCA also penalizes those who act in "deliberate ignorance of the truth or falsity of the information" and in "reckless disregard of the truth." The fact that Defendants are alleged to have strenuously supported the efficacy of Natrecor, even when there was no scientific proof supporting those claims, sufficiently establishes allegations of "reckless disregard of the truth."

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[2] This is not to say, as Defendants suggest, that this Court is "second-guess[ing] doctors' considered medical opinions." Mot. at 10. Rather, this Court acknowledges that the Complaint alleges that doctors did not, in fact, make considered medical judgments. Instead, the Complaint alleges that doctors prescribed Natrecor for outpatient use only because they were induced to do so by Defendants' misrepresentations.

Second, as to whether the Contractors' authorization of off-label reimbursement absolves Defendants, Plaintiff alleges that the only reason those Contractors authorized reimbursement was because of Defendants' misrepresentations. In particular, the Complaint alleges that "[i]n 2004 and 2005, Scios, without any scientific support for the efficacy of the serial infusions, urged Medicare Contractors to cover serial outpatient infusions. For example, Scios routinely touted both the safety and alleged efficacy results of the limited FUSION I study to the Medicare Contractors in an effort to support coverage." Comp. ¶ 106. As explained above, Plaintiff separately alleges that this FUSION I study did not in fact support the efficacy of outpatient use of Natrecor. In other words, Plaintiff alleges that the Contractors were duped in the same way that doctors were duped: they were told that certain medical evidence existed, when in fact it did not. Making inferences in favor of the non-moving party, as is required at this stage, Plaintiff has sufficiently alleged a violation of the False Claims Act.

3. Defendants' arguments under Rule 9(b)

Defendants also argue that the Complaint is insufficiently particular under Rule 9(b) of the Federal Rules. "[C]omplaints brought under the FCA must fulfill the requirements of Rule 9(b)." Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001). Specifically, Defendants argue that the complaint is inadequate for two reasons: (1) "the Complaint as a whole fails to identify the allegedly false claims with the particularity courts have required, instead using a formula to lump together all the prescriptions written during a six-year period;" and (2) "the Complaint fails to allege a causal connection of any sort between Scios and Natrecor prescriptions written months after Scios directed its sales force to limit promotion to hospital use." Mot. at 11-12.

a. Failure to sufficiently identify the false claims

Defendants make two arguments with regard to the identification of the false claims. First, Defendants argue that the Complaint itself does not specify the details of the thousands of claims that are alleged to have violated the FCA. Instead, the Complaint alleges a total estimate of the number of claims, and alleges that all these claims were submitted because of

Defendants' misrepresentations. Plaintiff submitted a database containing the details of the claims themselves, such as claim numbers, to Defendants in separate filing.

Second, Defendants argue that the algorithm used by Plaintiff to identify false claims is insufficiently accurate, and at most can be said to identify claims that "were *probably* false rather than identifying particular claims that actually *were* false." Id. at 12. While this algorithm is not mentioned in the Complaint, it is explained in a letter submitted to Defendants, and was used to compile the total number of allegedly false claims. This probabilistic approach to defining claims, argue Defendants, is insufficient.

Because this Court concludes that the Complaint on its face is sufficiently particular, this order does not address the adequacy of the algorithm.

Defendants contend that the allegations in the Complaint do not specify the details of the claims themselves, such as the names of the doctors or the date of the treatment, and therefore the Complaint is insufficiently particular. However, there appears to be a split of authority – none of it controlling – as to the proper approach to determining particularity in this context. Some courts, as Defendants argue, require the details of the claims themselves be pleaded with particularity, even if the fraudulent scheme itself is alleged with great particularity.[3] Other courts, however, focus on the allegations of fraudulent conduct and the scheme of misrepresentations, rather than on the details of the individual claims.[4]

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[3] See, e.g., United States ex rel. Duxbuty v. Ortho Biotech Prods., 579 F.3d 13, 30 (1st Cir. 2009) (finding a complaint to be sufficiently particular, albeit a "close call," where it provided "information as to the dates and amounts of the false claims"); United States ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11 (D. Mass. 2008) (explaining that after being dismissed for insufficient particularity, an amended complaint was adequately plead where it listed the 200 claims in addition to the drug codes used); United States ex rel. Serrano v. Oaks Diagnostics, Inc., 568 F. Supp. 2d 1136, 1143 (C.D. Cal. 2008) ("[T]he Ninth Circuit requires some specifics, such as the time, place, nature of the false statement, as well as the identities of the parties to the misrepresentation be present to comply with Rule 9(b) pleading standards.").

[4] See, e.g., United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 49 (D. Mass. 2001) ("[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the FCA have not placed the bar so high as to require pleading with total insight."); United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1049 (S.D. Tex. 1998) (holding relator satisfied Rule 9(b) by alleging the "basic framework, procedures, the nature of fraudulent scheme, and the financial arrangements and inducements among the parties and physicians that give rise to Relator's belief that fraud has occurred"); United States

This Court concludes that, given the purposes of Rule 9(b), the specifics of all claims are unnecessary at the pleading stage. The gravamen of this action concerns fraudulent inducement of doctors, and the Complaint provides exhaustive allegations relating to this fraud. In this context, the specifics of the claims themselves are somewhat less important. Instead, the case concerns the marketing activities of Defendants and whether they acted in reckless disregard of the truth. The allegations in the Complaint put defendants on sufficient notice of the nature of the action, and given the immense number of claims at issue, requiring them to be listed one-by-one in the Complaint is ungainly and unfair. While Plaintiff undoubtedly bears the burden of proof as to damages, Plaintiff need not conclusively meet this burden at the pleading stage.

This approach is in keeping with the purpose of Rule 9(b). The Ninth Circuit has explained that, in order to comply with Rule 9(b), allegations of fraud must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993). This standard has been met here. Plaintiff has alleged a thorough and complex series of actions which, if true, constitutes a violation of the False Claims Act. Indeed, Defendants do not argue that allegations regarding their conduct are insufficiently particular. Instead, Defendants focus on the fact that the individual claims for reimbursement are not identified. However, allegations of that nature are by no means necessary in order to Defendants to formulate their defense. Plaintiff is clear as to the wrongs it believes Defendants to have committed. While there may indeed be factual disputes as to which claims, if any, were the result of Defendants' fraudulent activity, it is not Plaintiff's burden to prove such causation at the pleading stage. Given the tremendous burden to fully identify such claims at the pleading stage, and the fact that Defendants have been fully apprised of what "is alleged to constitute the fraud charged," id., dismissal is not warranted.

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es rel. Pogue v. Am. Healthcorp., Inc., 977 F. Supp. 1329, 1332-33 (M.D. Tenn. 1997) (permitting relator to omit allegations concerning each instance of fraudulent conduct).

b. Failure to allege causation for claims submitted after March 2006

Defendants come close to conceding that claims submitted after March of 2006, when Medicare officially denied coverage for outpatient use of Natrecor, were "false" for purposes of the FCA. Mot. at 15; see also Comp. ¶ 110. However, Defendants argue that "the Complaint fails to plead the requisite causal nexus between *any* of Scios' alleged promotional activities and the submission of *any* particular claim." Mot. at 15. Specifically, with regard to post-March 2006 claims, Defendants explain that "nowhere in the Complaint's 34 pages is there a single allegation that Scios engaged in outpatient promotion *after* the summer of 2005." Id. While Defendants are correct, they miss the point of the Complaint. Even though the Complaint itself explains that Scios "terminate[d] the use of any promotional material or programming that directly conflicts with" a specialists' panel recommendation that off-label use not be prescribed in July of 2005, Comp. ¶ 104, the broader allegations suggest that the only reason any doctor prescribed Natrecor was because of Defendants' earlier promotion. In other words, while Defendants' termination of promotion is a step in the right direction from Plaintiff's perspective, the Complaint alleges that after many years of promotion, Defendants were not able to un-ring the bell. The Complaint alleges that Defendants' actions created the market for off-label use of Natrecor, and so alleges that all such uses can be traced back to Defendants' actions. Subsequent attempts shift course on their own do not absolve Defendants for earlier allegedly fraudulent activity.

4. Unjust Enrichment

The motion also seeks dismissal of Plaintiff's unjust enrichment claim. However, the motion does not present an independent basis for this conclusion. Instead, the motion argues that because the FCA claim fails, so too must the claim for unjust enrichment. Because this Court disagrees with Defendants' analysis of the FCA claim, their argument as to unjust enrichment must be rejected.

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Conclusion

For the reasons stated above, the motion to dismiss is DENIED.

IT IS SO ORDERED.

Dated: Dec. 23, 2009

CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE